

**Preliminary Amendment**

Serial No.: 10/051,719

Confirmation No.: 8633

Filed: 16 January 2002

For: ANTISEPTIC COMPOSITIONS AND METHODS

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**Remarks**

The above amendments have been made to remove the internal attorney docket number and replace it with the U.S. Patent Application Serial Number; and to correct typographical errors. No new matter has been added as a result of these amendments.

**Conclusion**

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if there are any questions regarding this Preliminary Amendment or if prosecution of this application may be assisted thereby.

Respectfully submitted for  
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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that this paper is being deposited with the United States Postal Service as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202, on this 21 day of August, 2002.

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APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS  
INCLUDING NOTATIONS TO INDICATE CHANGES MADE

Serial No.: 10/051,719

Docket No.: 57338US002

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Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted. Additionally, all amendments have been marked in bold typeface.

**In the Specification**

The paragraph beginning at page 11, line 13, has been amended as follows:

-- Many references have described the preparation of "iodophors," which are complexes of elemental iodine or triiodide with certain carriers. These iodophors function to not only increase the iodine solubility but to reduce the level of free molecular iodine in solution and to provide a type of sustained release reservoir of elemental iodine. Iodophors are known using carriers of polymers such as polyvinylpyrrolidone, copolymers of N-vinyl lactams with other unsaturated monomers such as, but not limited to, acrylates and acrylamides, various polyether glycols including polyether-containing surfactants such as nonylphenoethoxylates and the like, polyvinyl alcohols, polycarboxylic acids such as polyacrylic acid, polyacrylamides, polysaccharides such as dextrose, and the like, and combinations thereof. A preferred group of iodophors include polymers such as a polyvinylpyrrolidone (PVP), a copolymer of N-vinyl lactam, a polyether glycol (PEG), a polyvinyl alcohol, a polyacrylamide, a polysaccharide, and combinations thereof. Also reported in U.S. Pat. No. [4,957,975] 4,597,975 (Woodward et al.) are protonated amine oxide surfactant-triiodide complexes that are also suitable iodophors for use in the present invention. Various combinations of iodophores can be used in the compositions of the present invention. - -

The paragraph beginning at page 14, line 11, has been amended as follows:

- - The hydroxycarboxylic acid buffers of the present invention include preferably beta- and alpha-hydroxy acids (BHAs, AHAs, respectively, collectively referred to as hydroxy acids (HAs)), salts thereof, lactones thereof, and/or derivatives thereof. These may include mono-, di-,

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and tri- functional carboxylic acids. Particularly preferred are HAs having 1 or 2 hydroxyl groups and 1 or 2 carboxylic acid groups. Suitable HAs include, but are not limited to, lactic acid, malic acid, citric acid, 2-hydroxybutanoic acid, 3-hydroxybutanoic acid, mandelic acid, gluconic acid, tartaric acid, salicylic acid, as well as derivatives thereof (e.g., compounds substituted with hydroxyls, phenyl groups, hydroxyphenyl groups, alkyl groups, halogens, as well as combinations thereof)). Preferred HAs include lactic acid, malic acid, and citric acid. These acids may be in D, L, or DL form and may be present as free acid, lactone, or salts thereof. Other suitable HAs are described in U.S. Pat. No. 5,665,776 (Yu et al.). The preferred HAs for use with iodine and in particular with povidone-iodine are lactic and malic acid. Various combinations of hydroxycarboxylic acids can be used if desired. - -

The paragraph beginning at page 17, line 21, has been amended as follows:

- - Examples of suitable hydrophobic and hydrophilic monomers are described in Applicants' Assignee's copending U.S. Patent Application Serial No. 10/052,158 [\_\_\_\_], filed on even date herewith, entitled FILM-FORMING COMPOSITIONS AND METHODS [(Attorney Docket No. 57339US002)]. - -

The paragraph beginning at page 18, line 3, has been amended as follows:

- - Preferred film-forming polymers are cationic polymers, particularly those that include side-chain functional amine groups. Examples of such groups include protonated tertiary amines, quaternary amines, amine oxides, and combinations thereof. Preferred such polymers are described in Applicants' assignee's copending U.S. Patent Application Serial No. [\_\_\_\_] 10/052,158, filed on even date herewith, entitled FILM-FORMING COMPOSITIONS AND METHODS [(Attorney Docket No. 57339US002)]. - -

The paragraph beginning at page 23, line 11, has been amended as follows:

-- 6. *Alkyl Polyglucosides*. Alkyl polyglucosides, such as those described in U.S. Pat. No. 5,951,993 (Scholz et al.), starting at column 9, line 44, are compatible with the film-forming polymers of the present invention and may contribute to polymer stability. Examples include glucopon 425, which has a (C8-C16)alkyl chain length with an average chain length of 10.3 carbons and 1-4 glucose units. --

The paragraph beginning at page 28, line 2, has been amended as follows:

-- In addition to film-forming polymers and surfactants, a variety of other ingredients may be added to the antiseptic compositions of the present invention for desired effect. These include, but are not limited to, skin emollients and humectants such as those described in U.S. Pat. No. 5,951,993 (Scholz et al.), fragrances, colorants, tackifiers, plasticizers, etc. --

The paragraph beginning at page 42, line 28, has been amended as follows:

-- Compositions were evaluated for their potential for eye irritation compared to commercially available antiseptics: BETADINE Surgical Scrub (7.5% povidone-iodine) and BETADINE Sterile Ophthalmic Prep Solution (5% povidone-iodine). The test involved instilling into the eyes of adult New Zealand White albino rabbits weighing 2.0-3.5 Kg of either sex. Proper husbandry of the animals prior to testing is ensured including clean housing, high fiber rabbit diets (No. 5326 Purina Mills, Inc.), proper clean watering, proper environmental control (16°C-22°C, 30%-70% relative humidity, and a 12 hour light/12 hour dark cycle). All animals were acclimated for at least 5 days and were given various cage-enrichment devices. Eyes were examined using sodium fluorescein dye on the day before the test material administration to ensure no sign of corneal injury or eye abnormality was present. Each test material was administered to three rabbits with 0.1 mL of undiluted test material/eye for two consecutive days.

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The eyelids were gently held together for 1 second before releasing to prevent loss of the material. The eyes of the rabbits remained unflushed for approximately 24 hours following instillation of the test material. The right eye of each animal was treated while the left eye remained untreated as a control. The eyes were examined for ocular irritation at 1, 4, 24, 48, and 72 hours after their respective treatment. Additional observations were made at 96 and 120 hours if irritation was present at 72 hours. Sodium Fluorescein was used to aide in revealing possible corneal injury for each animal beginning with the 24-hour examination and each continuing examination until a negative response was attained. Irritation was scored using the Ocular Draize Technique (J. H. Draize: "Dermal Toxicity," ["**Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics**"] *Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics*, Association of Food and Drug Officials of the U.S., 1959, pages 46-59 [59-51]) with some modification. The maximum total score for these examples was the sum of scores obtained only from the conjunctivae. Total maximum score possible is 60 (20 per eye times three eyes). Notes were made with respect to the Cornea opacity, but this was not included in the scoring. --